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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/646,383	08/21/2003	Vincent G. Copa	AMS0008/US	9726

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EXAMINER

YABUT, DIANE D

ART UNIT	PAPER NUMBER
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3734

DATE MAILED: 08/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/646,383

Applicant(s)

COPA ET AL.

Examiner

Diane Yabut

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 15-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>8/23/04; 2/17/04</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-14, drawn to an anastomosis device, classified in class 606, subclass 153.
 - II. Claims 15-25, drawn to method for performing anastomosis, classified in class 606, subclass 144.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case, the process can be practiced by another anastomosis device, such as one involving sutures.
3. Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.
4. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

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5. The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

6. Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

8. During a telephone conversation with Daniel Schulte on Wednesday, July 26, 2006 a provisional election was made without traverse to prosecute the invention of Group I directed towards Claims 1-14. Affirmation of this election must be made by applicant in replying to this Office action. Claims 15-25, which are directed towards Group II, are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Information Disclosure Statement

9. The information disclosure statement (IDS) submitted on 23 August 2004 is acknowledged. In addition, the IDS submitted on 17 February 2004 is acknowledged. The submissions are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements are being considered by the examiner.

Specification

10. The abstract of the disclosure is objected to because it should include the features of the movable elongate structures, such as the tines, as well as the method of holding opposing severed urethral tissues together. Correction is required. See MPEP § 608.01(b).

11. The disclosure is objected to because of the following informalities: On page 11, line 16, it reads "tines 29" and should be changed to --tines 33--.

Appropriate correction is required.

Claim Objections

12. Claims 5 and 6 are objected to because of the following informalities: In lines 2-3 of both Claims 5 and 6, it is unnecessary to repeat "a hollow, elongate, flexible catheter body having a proximal end an a distal end" as well as "an inflatable balloon at the distal end" as these limitations are present in independent Claim 1, and therefore should be omitted. On line 5 of Claims 5-6 it reads "a drainage lumen" and should be changed to --the drainage lumen--, as it is dependent on Claim 1. Appropriate correction is required.

Note: Claim 6 reads "inflation means" in line 4 of the claim, "drainage means" in line 6 of the claim, and "tissue approximating means" in line 8 of the claim, which do not invoke 35 U.S.C. § 112, 6th paragraph, as they are not in the proper form.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. Claims 1-3,7-10, and 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Bander** (U.S. Patent No. **6,299,598**) in view of **Seiba** (U.S. Pub. No. **20030229364**).

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Claims 1-3, 7-10, and 12-14: Bander discloses a hollow, elongate, flexible catheter body **10** having a proximal end and a distal end, an inflatable balloon **24** at the distal end, and a drainage lumen (Figure 4 and col. 3, lines 32-40). Bander discloses the claimed device except for a tissue approximating structure, or means, on the catheter body on a proximal side of the balloon at a location to contact severed tissue.

Seiba teaches a tissue approximating structure **200** with multiple, opposing tines on a catheter body **220** on a proximal side of a balloon **240**, and is beneficial during anastomosis in a radical retropubic prostatectomy to engage the urethra and bladder and facilitate fluid flow and patency of the two conduits (Figure 9B and page 2, paragraph 25). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a tissue approximating structure, as taught by Seiba, to Bander in order to make the device applicable to anastomosis using a device that facilitates fluid flow and patency of the two conduits.

15. Claims 4-6, 11 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Bander** (U.S. Patent No. **6,299,598**) and **Seiba** (U.S. Pub. No. **20030229364**), as applied to Claims 1, 3, and 9 above, and further in view of **Biggs et al.** (U.S. Patent No. **6,599,311**).

Claims 4-6, 11 and 14: Bander and Seiba disclose the claimed device, including an inflation lumen extending from the proximal end to the balloon (Bander, col. 4, lines 17-21), a drainage lumen connected to the distal end extending from a drainage aperture **14** at the distal end to a drainage port **16** at the proximal end (Bander, col. 3, lines 32-40), and both distal and proximal, movable elongate tines (Seiba, Figure 9B), except for

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the tines being positioned to extend through apertures in the hollow catheter body and an actuating mechanism that is connected to the tissue approximating means that can be extended and retracted from apertures in the catheter body, and the actuating mechanism extends through a lumen along a portion of the length of the device to the proximal end which actuates the tissue approximating means.

Biggs et al. teaches tines **266** being positioned to extend through apertures **264** in a hollow body catheter **260** (Fig 31B and col. 20, lines 1-7). Biggs et al. also teaches an actuating mechanism **202** that is connected to a tissue approximating means **204** that can be extended and retracted from apertures in the catheter body, and the actuating mechanism may extend through a lumen along a portion of the length of the device to the proximal end which actuates the tissue approximating means (Figures 24A-24B, col. 19 lines 1-10). Biggs et al. teaches that this mechanism allows for the anchoring device to be advanced into a passageway in a non-extended form until it reaches a position where it can be attached to tissue and may subsequently be extended through the apertures (col. 2, lines 62-67 and col. 3, lines 1-2). It would have been obvious to one of ordinary skill in the art at the time of invention to provide extendable tines through apertures in a hollow catheter and an actuating mechanism that is connected to and actuates the tissue approximating means, as taught by Biggs et al., to Bander and Seiba in order to move the catheter, or the device within the catheter, without being engaged to the tissue until it is at a desired location at which point the tines can be extended.

Conclusion

16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. **Orban, III** (U.S. Pub. No. **20050251155**) discloses an anastomosis device with opposing tines.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diane Yabut whose telephone number is (571) 272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on (571) 272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DY



MICHAEL J. HAYES
SUPERVISORY PATENT EXAMINER